

REMARKS

Rejection of Claims 18-24 and 27 Under 35 U.S.C. §112, First Paragraph

Claims 18-24 and 27 are rejected under 35 U.S.C. §112, first paragraph, because, according to the Office Action, the specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicants respectfully disagree. The Claims are directed to a method of inducing an immune response by administering a compound comprising a CpG dinucleotide and modulating that immune response by the addition of an immunomodulatory moiety. In support of the claims Applicants provided an example in the specification and three (3) additional examples in a Declaration filed on April 19, 2004, wherein the immunomodulatory moiety was either one of several phosphorothioate linked nucleotides or a 1,3-propanediol linker. However, according to the Office Action, one cannot conclude from the evidence provided, either in the specification or in the examples provided with the Declaration, that the increased immunomodulatory effect was indeed due to the abasic, deoxyuridine, or deoxynitropyrrole nucleotides or to the 1,3-propanediol linker because the effect could have been from the phosphorothioate linkages.

This is not an accurate interpretation of the data. As stated in the first sentence of Example 1, the oligonucleotides used, including the control CpG oligonucleotide without the immunomodulatory moiety, were PS-oligonucleotides. Thus, all the internucleotide linkages in the oligonucleotides were phosphorothioate linkages and that any immune response modulation seen in the data was due to the immunomodulatory moiety and not the phosphorothioate linkage.

Therefore, Applicants provide both *in vitro* and *in vivo* data for four (4) immunomodulatory moieties and provide ample support to enable one skilled in the art to practice the invention commensurate in scope with these claims. Additionally, although the Office Action correctly states that Yu et al. (Exhibit 3 of the Declaration) shows that the position of immunomodulatory moieties in relation to the CpG dinucleotide are critical to immunostimulatory function, Yu et al. was published after the filing date of the instant application and is thus neither prior art nor the state of the art at the time of the invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 18-24 and 27 Under 35 U.S.C. §112, Second Paragraph

Claims 18-24 and 27 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Office Action has rejected Claim 18 because the claim is drawn to a 1,3-propanediol linker which may be "substituted". Applicants respectfully disagree. At page 13, lines 1 through 31, for example, the specification defines the term "substituted" and provides examples of suitable substituents. Applicants submit, therefore, that the term "substituted", is defined by the specification and, when read in light of the specification, has definite meaning to one of ordinary skill in the art.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

Dated: November 19, 2004

By Joseph C. Zuccherro
Joseph C. Zuccherro
Registration No. 55,762

Keown & Associates
500 West Cummings Park
Suite 1200
Woburn, MA 01801
Telephone: 781-938-1805
Facsimile: 781-938-4777